

Response to Final Office Action
Docket No. 020.0337.US.CONREMARKS

Claims 1, 12, 21, 22, 29, and 44 have been amended. No new matter has been entered. Claims 1-54 are pending and remain in the application.

Claims 1, 12, 21, 22, 29, and 44 have been amended to present the rejected 5 claims to recite proper antecedent basis and to better distinguish over the cited references established in the new rejections in the Final Office action. Accordingly, good and sufficient reasons why the amendments were necessary and were not earlier presented are present. 37 C.F.R. 1.116.

The references in the Information Disclosure Statement (IDS) mailed on 10 July 21, 2005 were partially signed. The listed foreign patent document, WO 99/55226, to Medtronic Physio-Control Manufacturing Corp., was not acknowledged. Acknowledgement of the IDS and entry of the cited art references are requested.

Claims 1-54 stand rejected under 35 U.S.C. § 103(a) as being obvious 15 over U.S. Patent No. 6,168,563 to Brown ("Brown"), in view of U.S. Patent No. 4,852,570 to Levine ("Levine"). Applicant traverses the rejection.

To establish a *prima facie* case of obviousness, the examiner has the burden of proving that (1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary 20 skill in the art, to modify the reference or combine the reference teachings; (2) there is a reasonable expectation of success; and (3) the combined references teach or suggest all the claim limitations. MPEP § 2143. A *prima facie* of obviousness case has not been shown.

The Brown patent teaches a system and method that enable a healthcare 25 provider to monitor and manage a health condition of a patient using a self-care health monitoring system (Abstract; Fig. 1; Col. 11, lines 22-23). A computer server, referred to as a clearinghouse computer facility, includes a script generator for generating a script program that is executable by a remotely-programmable apparatus, referred to as a data management unit (Col. 9, lines 27-29 and 33-35). 30 The server includes a database for use in storing the script program and patient

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responses to queries (Col. 9, lines 38-40). In an alternative embodiment, a speech synthesizer audibly communicates the queries and a speech recognizer receives spoken responses to the queries (Col. 9, line 48-52).

At least one monitoring device produces measurements of a physiological condition of an individual, which are stored in a memory and transmitted to the server with responses to the queries (Col. 9, line 61-Col. 10, line 2). The clearinghouse computer facility facilitates communication between the individual and his or her healthcare professional by providing the healthcare professional with standardized reports via facsimile, which indicate both the current condition and condition trends of the individual (Col. 15, lines 5-11). Preferably, the data supplied to the clearinghouse consists of raw data that was stored in the memory of the data management unit without further processing (Col. 15, lines 44-49).

A healthcare professional can operate a computer to access the data in the clearinghouse computing facility, which can be processed, analyzed, printed or displayed using commercially available or custom software (Col. 16, lines 32-42). Alternatively, various types of analyses may be performed by the clearinghouse computing facility with the results being transmitted to the remotely-located healthcare professional (Col. 16, lines 42-45).

The Levine patent teaches comparative medical-physical analysis. An individual is monitored in conventional fashion by many different transducers to read conventional body functions, including blood pressure, heart beat, respiration, urine analysis, blood circulation, blood composition, skin color, saliva, perspiration count, EKG, and many others (Col. 4, lines 4-11). Each such function is monitored by a transducer, or entered by a keyboard-terminal into a gating system of a recorder (Col. 4, lines 11-13). Each of the electrical signals for the various tests and other information is directed to the gating system for enabling sequential recording as microrecordings on a small card size medical history (Col. 2, line 64-Col. 3, line 10; Col. 4, lines 54-59).

Each different group of physiological tests is taken at frequent short term intervals, such as every four or six months (Col. 3, lines 10-15). Each such group may include the results of up to one hundred or more tests (Col. 3, lines 13-16).

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As a result, the card size medical record may contain a comprehensive compilation of frequently made groups of physiological tests and medical information about an individual over a long time period (Col. 3, lines 17-23).

Having such a comprehensive medical history of that individual, a physician can
5 compare the results of many like tests taken periodically over long time periods, and therefore be more able to determine any changes or "trends" that have developed, or are in the process of development that might indicate an adverse condition (Col. 3, lines 30-45).

First, there is no suggestion or motivation to modify or combine the
10 references. Brown teaches remote health care monitoring using a clearinghouse computer facility remotely connected to a data management unit, which produces measures of a physiological condition that are stored and transmitted to the clearinghouse. The clearinghouse provides standardized reports that indicate both current condition and condition trends and can perform various types of analyses
15 for remotely-located healthcare professionals. In contrast, Levine teaches monitoring conventional body functions and other information, which is sequentially microrecorded on a small card size medical history. The card history can be compiled into a comprehensive medical history that a physician can compare over long time periods to determine any changes or "trends."

20 One of ordinary skill in the art would not be inclined to modify or combine these references. In Brown, the focus is on providing remote patient monitoring; whereas, in Levine, the focus is on recording body functions and other data on a credit card size medical record at frequent "short term" intervals, that is, every four or six months. Brown teaches a central server for various
25 system users, which can receive, store, and transmit digitally-encoded information to an intended recipient. Levine teaches away from a centralized clearinghouse by teaching a card history that must be carried and maintained by each patient to enable the microrecorded information to be used by physicians. Levine does not teach or suggest recognizing a trend indicating disease onset. Rather, Levine
30 teaches "obtaining and making available in useful form more physiological information about an individual" through the cumulative results of periodically

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made tests stored on the card histories (Col. 2, lines 5-45). Brown already teaches obtaining and making available physiological measures, but through a centrally managed clearinghouse, rather than a medical card that could be lost. Thus, there is no suggestion or motivation to modify or combine.

5 Arguably, a reasonable expectation of success exists. Combining Levine's teachings would add a further source of patient information through the card histories into the self-care health monitoring system taught by Brown, even though the same type of patient monitoring could already be provided by the data management unit of Brown.

10 Nevertheless, the combined references fail to teach or suggest all the claim limitations. Brown teaches providing standardized reports, which indicate current patient condition and condition trends. Levine teaches repeatedly obtaining short term changes in physiological functioning as an aid in diagnosing illness and malfunction, where an extensive compilation of test and medical data is reviewed

15 at compared at longer term intervals to reveal changes and "trends." Combining the teachings of Brown and Levine provides patient condition and trend reporting based on patient data obtained through self-care health monitoring and from card size medical histories.

Independent Claims 1, 29, and 44 have been amended to clarify the

20 inventive subject matter and better distinguish over Brown and Levine. For instance, independent Claim 1 recites an analysis module analyzing one or more of the collected measures sets in the patient care record for the individual patient relative to one or more other collected measures sets stored in the database to determine a patient status indicator of patient wellness to *automatically* recognize

25 a trend indicating disease onset, progression, regression, and status quo in patient well being and to *automatically* determine whether medical intervention is necessary (emphasis added). Claim 29 recites analyzing one or more of the collected measures sets in the patient care record for the individual patient relative to one or more other collected measures sets stored in the database to determine a

30 patient status indicator of patient wellness to *automatically* recognize a trend indicating disease onset, progression, regression, and status quo in patient well

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being and to *automatically* determine whether medical intervention is necessary (emphasis added). Claim 44 recites code for analyzing one or more of the collected measures sets in the patient care record for the individual patient relative to one or more other collected measures sets stored in the database to determine a 5 patient status indicator of patient wellness to *automatically* recognize a trend indicating disease onset, progression, regression, and status quo in patient well being and to *automatically* determine whether medical intervention is necessary (emphasis added). Such limitations are neither taught nor suggested by the Brown-Levine combination, which requires the healthcare provider to request the 10 determination of a condition trend. No new matter has been entered. Support can be in the specification on p. 4, lines 25-28; p. 15, line 21-p. 16, line 3; p. 30, line 3-p. 31, line 14.

Accordingly, a *prima facie* case of obviousness has not been shown for independent claims 1, 29, and 44. Claims 2-28 are dependent on Claim 1 and are 15 patentable for the above-stated reasons and as further distinguished by the limitations recited therein. Claims 30-43 are dependent on Claim 29 and are patentable for the above-stated reasons and as further distinguished by the limitations recited therein. Claims 45-54 are dependent on Claim 44 and are patentable for the above-stated reasons and as further distinguished by the 20 limitations recited therein. Withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 1-54 stand rejected under 35 U.S.C. § 103(a) as being obvious over Brown, in view of U.S. Patent No. 6,234,964 to Iliff ("Iliff"). Applicant traverses the rejection. A *prima facie* of obviousness case has not been shown.

25 The Iliff patent teaches a disease management system and method for assessing the health of a patient having a disease and optimizing disease therapy based on a health assessment of the patient (Col. 2, lines 43-48). A disease management module (DMM) performs automated medical services for users of a medical management system (Col. 5, lines 50-54). The DMM process manages a 30 disease or condition of a patient (Col. 8, lines 20-22). The process obtains current health data from the patient in three forms: subjective, that is, as perceived or felt

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by the patient; objective, that is, as measured by the patient, typically with an instrument; and side effects noted by the patient (Col. 18, lines 15-20). These health measurements are then used to analyze the current health state (Col. 18, lines 21-22). A critical curve is defined as a plot of a health measurement against 5 time that is used to identify significant changes in health state (Col. 19, lines 30-34). When the trend line indicates that the patient's health curve is reaching a critical point, the DMM can change the therapy or notify the patient's physician (Col. 21, lines 5-8).

First, there is no suggestion or motivation to modify or combine the 10 references. Brown teaches remote health care monitoring using a clearinghouse computer facility remotely connected to a data management unit, which produces measures of a physiological condition that are stored and transmitted to the clearinghouse. The clearinghouse provides standardized reports that indicate both current condition and condition trends and can perform various types of analyses 15 for remotely-located healthcare professionals. In contrast, Iliff teaches disease management directed to the continuing medical care of a patient who has been diagnosed with a specific disease. The system performs disease management in a fully automated manner using periodic interactive dialogs with the patient to obtain health state measurements, to evaluate and assess patient disease state 20 progress, to review and adjust therapy to optimal levels, and to give the patient medical advice.

One of ordinary skill in the art would not be inclined to modify or 25 combine these references. In Brown, the focus is on providing remote patient monitoring for use by health care providers; whereas, in Iliff, the focus is on provide disease management to patients. Brown teaches providing standardized current condition and condition trend reports and performing various types of analyses for remotely-located healthcare professionals. Iliff teaches away from a healthcare professional-oriented clearinghouse by teaching a disease management system that promotes patient health in an automated manner that reduces costly 30 medical intervention. Where Brown favors health care provider involvement, Iliff favors patient health management autonomy. Thus, there is no suggestion or

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motivation to modify or combine.

Arguably, a reasonable expectation of success exists. Combining Iliff's teachings would add patient management and therapy optimization into the self-care health monitoring system taught by Brown.

5 Nevertheless, the combined references fail to teach or suggest all the claim limitations. Brown teaches providing standardized reports, which indicate current patient condition and condition trends. Iliff does not teach or suggest recognizing a trend indicating disease onset. Rather, Iliff teaches assessing the health and optimizing the therapy of a patient already having a disease. Combining the
10 teachings of Brown and Iliff provides patient condition and trend reporting based on patient data obtained through self-care health monitoring for a patient already known to have a health problem.

Independent Claims 1, 29, and 44 have been amended to clarify the inventive subject matter and better distinguish over Brown and Iliff. For instance,
15 independent Claim 1 recites a medical device having a sensor for *autonomously* monitoring at least one physiological measure of an individual patient and regularly recording measures sets that each comprise patient information; and an analysis module analyzing one or more of the collected measures sets in the patient care record for the individual patient relative to one or more other
20 collected measures sets stored in the database to determine a patient status indicator of patient wellness to *automatically* recognize a trend indicating disease onset, progression, regression, and status quo in patient well being and to *automatically* determine whether medical intervention is necessary (emphasis added). Claim 29 recites providing a medical device having a sensor for
25 *autonomously* monitoring at least one physiological measure of an individual patient; and analyzing one or more of the collected measures sets in the patient care record for the individual patient relative to one or more other collected measures sets stored in the database to determine a patient status indicator of patient wellness to *automatically* recognize a trend indicating disease onset,
30 progression, regression, and status quo in patient well being and to *automatically* determine whether medical intervention is necessary (emphasis added). Claim 44.

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recites code for a medical device having a sensor for *autonomously* monitoring at least one physiological measure of an individual patient; and code for analyzing one or more of the collected measures sets in the patient care record for the individual patient relative to one or more other collected measures sets stored in

5 the database to determine a patient status indicator of patient wellness to *automatically* recognize a trend indicating disease onset, progression, regression, and status quo in patient well being and to *automatically* determine whether medical intervention is necessary (emphasis added). Such limitations are neither taught nor suggested by the Brown-Iliff combination, which requires the patient to

10 obtain physiological measurements. No new matter has been entered. Support can be in the specification on p. 10, lines 2-29; p. 4, lines 25-28; p. 15, line 21-p. 16, line 3; p. 30, line 3-p. 31, line 14.

Accordingly, a *prima facie* case of obviousness has not been shown for independent claims 1, 29, and 44. Claims 2-28 are dependent on Claim 1 and are

15 patentable for the above-stated reasons and as further distinguished by the limitations recited therein. Claims 30-43 are dependent on Claim 29 and are patentable for the above-stated reasons and as further distinguished by the limitations recited therein. Claims 45-54 are dependent on Claim 44 and are patentable for the above-stated reasons and as further distinguished by the

20 limitations recited therein. Withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

The prior art made of record and not relied upon has been reviewed by the applicant and is considered to be no more pertinent than the prior art references already applied.

25 Claims 1-54 are believed to be in condition for allowance. Entry of the foregoing amendments is requested. Reconsideration of the claims, withdrawal of the finality of the Office action and a Notice of Allowance is earnestly solicited. Please contact the undersigned at (206) 381-3900 regarding any questions or concerns associated with the present matter.

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Respectfully submitted,

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